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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/027,681

12/21/2001

T. Daniel Gross

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08/16/2010

WORKMAN NYDEGGER
1000 EAGLE GATE TOWER,
60 EAST SOUTH TEMPLE
SALT LAKE CITY, UT 84111

EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

08/16/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/027,681	Applicant(s) GROSS ET AL.	
	Examiner DIANE YABUT	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-7 and 28-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-7 and 28-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/17/10; 7/30/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/17/2010 has been entered.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on 05/17/2010 and 07/30/2010 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. Claims 3-7 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Asnis** (U.S. Patent No. **5,059,201**) in view of **Makower et al.** (U.S. Patent No. **6,090,063**).

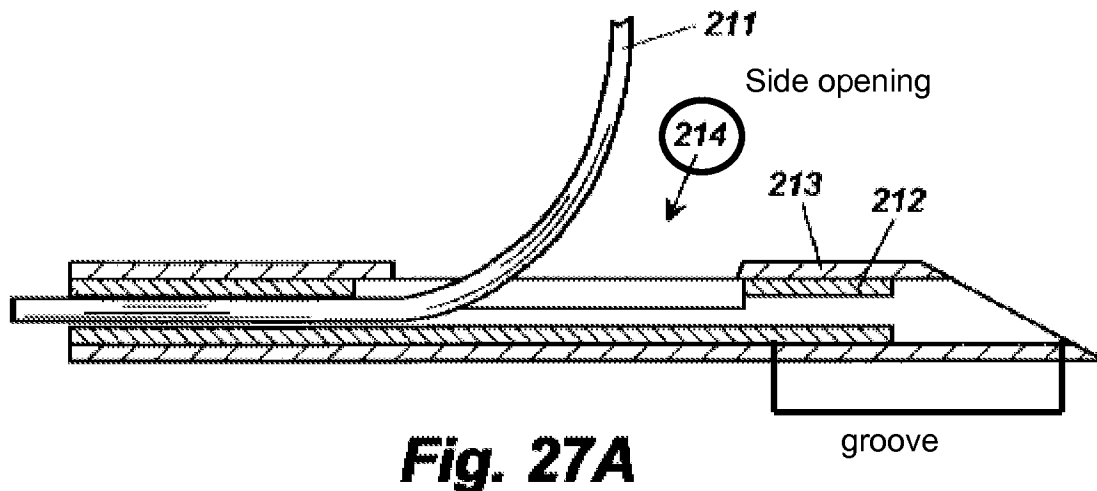
Asnis discloses a shaft **24** having a proximal end and a distal end and a lumen/bore extending from the proximal end toward the distal end and an axis therebetween, the shaft having a groove (lumen) formed in a side thereof, the groove extending from the distal end toward the proximal end and being in communication with an opening formed in the side (proximal tip opening) of the shaft, the opening disposed proximal the distal end of the shaft, a cutting member **102** (cutting surfaces **106** or **108** which face proximally, Figures 3-4) slidably disposed within the shaft and having a lumen defined therein, a suture retainer **202** slidably disposed within the shaft and within the cutting member, the suture retainer having a suture protector **206** in an exterior surface of the suture retainer, the suture protector extending from a retainer distal end toward a retainer proximal end, and a handle (any of portions **308**, **350**, or **352**) disposed adjacent the proximal end of the shaft including independently operable first **208** and second **304** levers each slidably received within the handle, the first lever operatively coupled to the suture retainer to move the suture retainer within the shaft and within the cutting member and the second lever operatively coupled to the cutting member to move the cutting member within the shaft and around the suture retainer to cut the suture and being transverse to the handle, and extending through the handle (see Figures 1, 3-4, 6, and 10-12). A biasing member **338** is in communication with the second lever, and therefore the cutting member (Figure 8).

Asnis does not expressly disclose the shaft opening including a proximal edge, the cutting member disposed within the shaft having an opening on its side in communication with the lumen and disposed proximal the distal end of the cutting member in communication with the lumen and disposed proximal the distal end of the cutting member, the opening of the cutting member having a distal edge, wherein the distal edge of the cutting member is moved into proximity with the proximal edge of the shaft opening to cut the suture. Asnis also does not expressly disclose the opening of the shaft being formed in a side in close proximity to the distal end of the shaft and formed proximal to the groove, and the groove communicating with the shaft lumen distal to the opening, the groove in communication with both the lumen and the side opening.

Makower et al. teach an outer shaft **213** having a lumen and a side opening including a proximal edge **214** and being in close proximity to the distal end of the shaft and formed proximal to a groove distal to the opening, the groove communicating with the shaft lumen distal to the opening, the groove in communication with both the lumen and the side opening, and an inner shaft **212** disposed within the outer shaft having an opening on its side in communication with the lumen and disposed proximal the distal end of the cutting member in communication with the lumen and disposed proximal the distal end of the cutting member, the opening of the cutting member having a distal edge **215**, wherein the distal edge of the cutting member is actuated and moved into proximity with the proximal edge of the shaft opening to cut a suture **211** due to the sharpened edges (Figures 27A-27B; col. 16, line 64 to col. 17, line 18). It would have

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been obvious to one of ordinary skill in the art at the time of invention to provide a proximal edge on the opening of the shaft that moves toward a distal edge of an opening in the cutting member of Asnis, as taught by Makower et al., in order to facilitate removal of the suture after threading through tissue.



5. Claims 29-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Asnis** (U.S. Patent No. **5,059,201**) in view of **Makower et al.** (U.S. Patent No. **6,090,063**) and **Elkus** (U.S. Patent No. **5,462,562**).

Asnis discloses a shaft **24** having a proximal end and a distal end and an axis therebetween, the shaft having a bore (lumen) formed in a side thereof, the groove extending from the distal end toward the proximal end and being in communication with an opening formed in the side (proximal tip) of the shaft, the opening disposed proximal the distal end of the shaft, a cutting member **102** (cutting surfaces **106** or **108** which face proximally, Figures 3-4) slidably disposed within the shaft and having a lumen defined therein, a suture retainer **202** slidably disposed within the shaft and within the

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cutting member, the suture retainer having a suture protector **204** including a channel **206** defined in the exterior surface, the suture protector extending from a retainer distal end toward a retainer proximal end, and a handle (any of portions **308**, **350**, or **352**) disposed adjacent the proximal end of the shaft including independently operable first **208** and second **304** levers each slidably received within the handle, the first lever operatively coupled to the suture retainer to move the suture retainer within the shaft and within the cutting member and the second lever operatively coupled to the cutting member to move the cutting member within the shaft and around the suture retainer to cut the suture and being transverse to the handle, and extending through the handle (see Figures 1, 3-4, 6, and 10-12). A biasing member **338** is in communication with the second lever, and therefore the cutting member (Figure 8).

Asnis does not expressly disclose the shaft opening including a proximal edge, the cutting member disposed within the shaft having an opening on its side in communication with the lumen and disposed proximal the distal end of the cutting member in communication with the lumen and disposed proximal the distal end of the cutting member, the opening of the cutting member having a distal edge, wherein the distal edge of the cutting member is moved into proximity with the proximal edge of the shaft opening to cut the suture. Asnis also does not expressly disclose the opening of the shaft being formed in a side in close proximity to the distal end of the shaft and formed proximal to the groove, and the groove communicating with the shaft lumen distal to the opening, the groove in communication with both the lumen and the side opening.

Makower et al. teach an outer shaft **213** having a lumen and a side opening including a proximal edge **214** and being in close proximity to the distal end of the shaft and formed proximal to a groove distal to the opening, the groove communicating with the shaft lumen distal to the opening, the groove in communication with both the lumen and the side opening, and an inner shaft **212** disposed within the outer shaft having an opening on its side in communication with the lumen and disposed proximal the distal end of the cutting member in communication with the lumen and disposed proximal the distal end of the cutting member, the opening of the cutting member having a distal edge **215**, wherein the distal edge of the cutting member is actuated and moved into proximity with the proximal edge of the shaft opening to cut a suture **211** due to the sharpened edges (Figures 27A-27B; col. 16, line 64 to col. 17, line 18). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a proximal edge on the opening of the shaft that moves toward a distal edge of an opening in the cutting member of Asnis, as taught by Makower et al., in order to facilitate removal of the suture after threading through tissue.

Asnis also discloses a fitting **26** at the distal end of the shaft **24** the fitting having a fixture fitting end, a fitting proximal end, and a fitting groove **46** extending from the fitting distal end toward the fitting proximal end, the fitting groove and the groove being aligned (Figure 1). However, Asnis does not disclose the fitting being received within the bore of the shaft.

Elkus teaches a suture passer with a fitting **13** fixed within a bore of a shaft **10** (Figures 1-3). It would have been obvious to modify the fitting of Asnis to be received

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within the bore of the shaft to reduce the profile of the distal end within tissue to clear the surgical site.

Response to Arguments

6. Applicant's arguments filed 05/17/2010 have been fully considered but they are not persuasive.

Applicant argues that Asnis does not disclose the opening of the shaft being formed in a side in close proximity to the distal end of the shaft and formed proximal to the groove, and the groove communicating with the shaft lumen distal to the opening, the groove in communication with both the lumen and the side opening. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. Makower et al. teach an outer shaft **213** having a lumen and a side opening including a proximal edge **214** and being in close proximity to the distal end of the shaft and formed proximal to a groove distal to the opening, the groove communicating with the shaft lumen distal to the opening, the groove in communication with both the lumen and the side opening. It would have been obvious to one of ordinary skill in the art at the time of invention to provide a proximal edge on the opening of the shaft that moves toward a distal edge of an opening in the cutting member of Asnis, as taught by Makower et al., in order to facilitate removal of the suture after threading through tissue.

Conclusion

7. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **DIANE YABUT** whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/TODD E. MANAHAN/
Supervisory Patent Examiner, Art Unit 3734